

REMARKS

By this amendment, claims 1-5 have been cancelled, claims 6-25 have been added, the drawings have been amended, and a new Abstract is submitted to place this application in condition for allowance.

In response to the objection to the specification, a substitute specification and the appropriate marked up version are submitted herewith and corrected drawings are also submitted. Support for the Substitute Specification can be found in original Figures 1-5 and the original specification. No new matter has been added. These submissions overcome the Examiner's objections in this regard.

The cancellation of claims 1-5 effectively overcomes the rejection based on 35 U.S.C. § 112, second paragraph. Claims 6-25 are believed to comply with this statutory section and are fully supported by the original disclosure.

Addressing the prior art rejection, the Examiner rejected claims 1-5 as being unpatentable over 35 USC 103(a) and Goldstein, US Patent 4,867,686. The Examiner rejected claim 4 as being unpatentable over Goldstein, in view of Barrie et al., US Patent 5,803,746. The Examiner further rejected claim 5 as being unpatentable over Goldstein, in view of Van Winkle, US Patent 5,913,686.

In light of the submission of new claims 6-25, Applicant submits that the cited and relied upon prior art fails to establish a *prima facie* case of anticipation or obviousness.

More specifically and referring to claim 1, it would not have been obvious to one of ordinary skill in the art to modify the invention disclosed in Goldstein to include a substantially rigid base. Goldstein discloses a model for a human female breast with a transparent backing 14 comprising the same material used to form the skin membrane 12.

Goldstein, col. 3, lines 58-60. The opaque skin membrane 12 is an elastomeric membrane simulating human skin and may comprise any material that closely simulates human skin, see col. 2, line 58 to col. 3, line 14. The backing 14 and skin 12 materials should be thick and strong enough to withstand repeated pressures exerted on the model but should not detract from the realistic feeling thereof, see col. 3, lines 63-67.

Moreover, the opaquing means 22 comprises an opaque, pliable sheet material or an opaque elastomeric membrane with an adhesive coating 23, such as a paper or fabric sheet of adhesive-backed satin cloth and “other pliable sheet materials,” see col. 4, lines 14-31. The pliable opening means 22 is designed to be removably attached, so that it is “capable of repeated attachment and removal from the transparent backing member 14 for repeated use...”.

Thus, Goldstein does not disclose a substantially rigid back and cannot anticipate claim 1, 19, and 25. In fact, Goldstein teaches away from a such a back, and such modification would destroy Goldstein for its intended purpose, see col. 2, lines 3-19. Consequently, Goldstein cannot establish a *prima facie* case of obviousness against claim 1.

The secondary references do not supply the deficiencies in Goldstein, and even if combined therewith, the combination thereof would not establish obviousness.

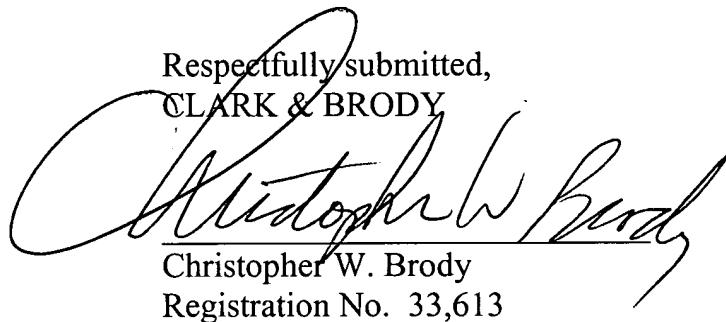
The Applicant respectfully submits that claims 6-25 are not anticipated or rendered obvious over the prior art of record and that the application is now in condition for allowance.

If the Examiner believes that an interview with Applicant's representative will expedite the prosecution of this application, Applicant requests that the Examiner contact the undersigned.

Again, reconsideration and allowance of this application is respectfully solicited.

A petition for a three-month extension of time is hereby made and a check in the amount of \$475.00 is enclosed herewith. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY



Christopher W. Brody
Registration No. 33,613

Customer No. 22902
1750 K Street NW, Suite 600
Washington DC 20006
Telephone: 202-835-1111
Facsimile: 202-835-1755

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Attachments: Substitute Specification (Clean Version)
Substitute Specification (Marked Version)
Substitute Abstract
Request for Approval of Drawing Corrections

SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND

Technical Field of the Invention

The present patent describes a simulator device invention discloses a model
5 for a human feminine mammary gland. More particularly, that is destined to guide
patient, nurses, doctors and the whole personnel of the medical, educational area and
lay population in the present invention discloses a model of a human feminine
mammary gland for the detection of pathological occurrences, through touch. It is
known the notorious difficulty of recognition of pathological occurrences of the human
10 feminine mammary gland, so much for own woman that solemnity examines herself, as
for the personnel of the medical area or the education area.

To solving such inconvenience, the present invention was developed, it is
composed by a didactic model that reproduces the intrinsic and extrinsic characteristics
of the feminine suckles, fixed on a frame or on a chart destined to the user's orientation.

15 The main characteristic of the this simulator device is the facilitation of the exam
of the mammary gland, for specialized people or not, once it propitiates, by touch, the
comparison, of inside and outside existent pathology simulators, with the possible
occurrences of abnormal signs, indicators of pathologies, verified in the woman suckles.

Background of the Invention

20 Inspection of the human female breast for identification of pathological
occurrences is widely practiced. However, the tactile detection of pathological
occurrences in the human female mammary gland present a variety of challenges
for women who perform self-examinations, as well as for medical personnel,
educators, and trainers.

Summary of the Invention

The present invention discloses a model of a human female breast. The model according to the present invention recreates the internal and external characteristics of the human female breast and may be used to train medical personnel, educators, women and others in detection of pathological occurrences in the human female breast.

In a preferred embodiment, the invention comprises a body comprising a filler material for simulating human female breast tissue, a base comprising a peripheral edge and an upper surface for supporting the filler material, a cover comprising a peripheral edge and a first surface, and at least one pathological simulator element disposed within the filler material, wherein the peripheral edge of the cover sealingly engages the peripheral edge of the base to contain the filler material between the first surface of the cover and the upper surface of the base, and wherein the base comprises a substantially rigid material.

In a further embodiment of the invention, a simulator comprises a body comprising a filler material for simulating human female breast tissue, a base comprising a peripheral edge and an upper surface for supporting the filler material, a cover comprising a peripheral edge and a first surface, wherein the peripheral edge of the cover sealingly engages the peripheral edge of the base to contain the filler material between the first surface of the cover and the upper surface of the base, and a frame comprising an upper surface, wherein the upper surface comprises a recess and wherein the base is secured in the recess, thereby securing the body to the frame.

In yet another embodiment of the invention, a body comprises a filler material for simulating human female breast tissue, a base comprising a peripheral edge and an upper surface for supporting the filler material, a cover comprising a peripheral edge and a first surface, an obdurate rib disposed within the filler material; and at least one pathological element disposed within the filler material, wherein the peripheral edge of the cover is placed in sealing engagement with the peripheral edge of the base such that the filler material is contained between the first surface of the cover and the upper surface of the base and wherein the obdurate rib is disposed in a portion of the filler material that does not contain any of said at least one pathological element.

Thus, the present invention facilitates the examination of the female mammary gland by providing a model that may be used to train and educate specialized medical personnel and educators, as well as lay persons and women who want to improve their ability to detect pathological occurrences and similar external and internal abnormalities in the female breast by palpitation and examination of the human female breast.

~~To allow visualization and a perfect understanding of the means of the present simulator device, illustrative drawings are enclosed, where:~~

~~The Figure 1 represents a frontal view of the simulator device for human feminine mammary gland put upon to the instructions chart.~~

~~The Figure 2 represents a frontal view of the simulator device for human feminine mammary gland.~~

~~The Figure 3 represents a section "A-A" of the simulator device for human feminine mammary gland.~~

~~The Figure 4 represents a section "A-A" of the simulator device for human feminine mammary gland put upon to the instructions chart.~~

5 **Brief Description of the Drawings**

The present invention is illustrated in the accompanying drawings in which:

~~The Figure 5 represents a view of the simulator device for human feminine mammary gland being put upon to the instructions~~
10 **1 is a front view of a human female breast mounted to an instructional** chart.

~~As it is shown in the above related figures, the simulator device for human feminine mammary gland has a body (1), put upon to a base (2) made by~~
Figure 2 is a front view of a human female breast simulator.

Figure 3 is a cross-sectional view taken along sectional line III-III in Figure
15 **2.**

Figure 4 is a cross-sectional view similar to Figure 3 but including the device on an instructional chart.

Figure 5 shows a human female breast simulator being mounted to an instructional chart.

20 **Detailed Description of the Preferred Embodiment**

As shown in Figures 3 and 4, the human female breast simulator comprises a body (1), a base (2), a filler material (3), and a cover (4). The base (2) supports the filler material (3) and comprises a rigid material, such as plastic, metal, wood,

formic, leather, rubber, etc., serving as and similar natural man-made materials. The
filler material (3) shape and support to the stuffing material (3) that gives volume to
the body (1); the stuffing material is normally prepared with many different material like
small particles, as grains, flakes, seeds, sawdust, sands body (1) and may comprise a
5 variety of granular, flaked, fibrous, or similar materials such as seeds, sawdust,
sand, flour, cotton, floss, plastic, seum, silicon, rubber, light weight metal, etc., or
similar materials in a gelatinous, gaseous, or liquid material, or still others state that
simulate the inside tissue of the mammary gland, having a texture that allows the
observation, for the touch, of the elements (5.a) and (5.b) simulators of existent
10 pathologies inside the body (1) simulates the inner tissue of the human female
breast. The filler material (3) provides a texture to the human female breast
simulator to enable training for the tactile detection of fixed and floating
pathological simulator elements (5A), (5B1), (5B2), (5C), which are disposed
within the filler material (3) and the body (1) of the human female breast
15 simulator.

These The fixed pathological simulator elements (5a), for its time, should come
fixed in A) are secured to the base (2) or in within the own stuffing filler material (3),
simulating rigid pathologies, in of the body (1). The fixed pathological simulator
elements (5A) may have an irregular and angular way, they must be made by wood,
20 mineral, metal, plastic, or other rigid material, as well as to present the elements (5.b)
loosened of the base, floating in the stuffing material (3), simulating non rigid
pathologies, with the internal material having spherical or round form, of flatter aspect,
made in soft and malleable material, shape as shown in Figures 2 and 3 and may be

manufactured from wood, minerals, metal, plastic, and similar rigid materials to stimulate the rigid pathologies that may occur in the human female breast. The floating pathological simulator elements (5B1), (5B2), (5C) may be disposed entirely within the filler material (3), unconnected to the base (2). The irregular-

5 shaped floating pathological simulator elements (5B1), (5B2) have an irregular shape of a somewhat flattened outline, while the spherical floating pathological simulator elements (5C) have a generally spherical or round shape. The floating pathological simulator elements (5B1), (5B2), (5C) may comprise a soft, malleable material such as cotton, rubber, plastic, vinyl, ~~seum, etc., or using gases, liquids,~~

10 ~~gelatinous materials, flakes, etc., preferably inside an elastic or similar spherical~~and similar materials in a gelatinous, gaseous, or liquid state that stimulate the non-rigid pathologies that may occur within the soft breast tissue of the human female breast. In a preferred embodiment of the invention, the floating pathological simulator elements (5B1), (5B2) may be disposed within an elastic or similar

15 casing or film.

~~The base (2) is preferably to fasten the simulator for the external borders to a flexible and elastic cover (4) that can be a response of human suckles and should be made in rubber, fabric, skin of animals, plastic, metallic screen, silicon, polyurethane, etc., forming the group that makes the contention of the stuffing material (3) and of the~~

20 ~~elements (5.a) and (5.b) simulators of pathologies.~~

In a preferred embodiment of the invention, the cover (4) is secured over the stuffing material (3) to the periphery of the base (2). The cover (4) is secured to the periphery of the base (2) to retain the stuffing material (3), the fixed

pathological simulator elements (5A), and the floating pathological simulator elements (5B1), (5B2) within the body 1 of the human female breast model. The cover (4) may comprise an elastic material such as rubber, fabric, animal skin, plastic, metallic screen, silicon, polyurethane, and similar materials that provide
5 and elastic texture and characteristic to the cover (5). The external coating of the flexible cover (4) may comprise a variety of colors and textures. The colors may correspond to the different colors of the human skin, or they may correspond to any other color. The colors may be in a variety of variations and combinations.

~~The~~As shown in Figures 1 and 2, the cover (4)~~2) of the body (1) has five~~
10 ~~defines areas (A, B, C, D, D, E), representing~~comprises five defined regions. Region
A represents the pigmented areola (6),~~the~~ and nipple (7)~~and the remaining of the~~
~~gland area represented in another.~~ Regions B through E represent the four
~~quadrants (B, C, D and E)~~of the glandular area of the human female breast.

The nipple (7) may also shows elements (5c, 5d and 5e) pathology simulators, in
15 ~~the figure 2 represented by three aleatoric points, with easy visual identification,~~
~~corresponding to the emersion of three secretion types after being the nipple pressed or~~
~~not with the fingers, as it: hemorrhage with dark coffee color (A1); blood hemorrhage~~
~~color (A2); crystalline hemorrhage like water (A3). To each element (5a, 5b, 5c, 5d,~~
~~and 5f) simulator corresponds a specific possible pathology occurrence.~~be configured
20 to represent pathological simulators (7A), (7B), (7C), as shown in Figure 2. The
nipple pathological simulators (7A), (7B), (7C) represent three aleatoric points,
each of which corresponds to a type of secretion. Each of the nipple pathological
simulators (7A), (7B), (7C) are susceptible to visual identification. Nipple

pathological simulator (7A) represents a hemorrhage with a dark coffee-like color.

Nipple pathological simulator (7B) represents a hemorrhage with a blood-like color. Nipple pathological simulator (7C) represents a hemorrhage with a crystalline, water-like color. The nipple pathological simulators (7A), (7B), (7C) may be emerged after the application of tactile pressure. Each of the base pathological simulator elements (5A), floating pathological simulator elements (5B), and the nipple pathological simulator elements (7A), (7B), (7C) represent a different pathological occurrence that may manifest itself within the human female breast.

The body (1) ~~can~~may be fastened in a frame (8) and be made by mounted to a frame (8), e.g., a chart, as shown in Figures 1, 4 and 5. The frame (8) may comprise a rigid material, such as cardboard, plastic, metal, wood, formic, leather, acrylic, etc., endowed with a lowering (9) in its central part for fitting the body (1), that should contain spaces (10) for orientations about providences that should be taken in case of detection of some of the simulate pathological occurrences, as well as spaces (11) for any information of public interest and publicity, leather, acrylic, and similar materials. In one embodiment of the invention, the frame (8) may contain a recess (9). When the body (1) is mounted to the frame (8), the body (1) may be placed in the recess (9) of the frame to secure it to the frame (8).

The frame (8) further includes a variety of medical procedures and instructions that should be followed in the event that a particular pathological occurrence is detected. The frame (8) may also include public interest information, advertising, and similar marketing and informational material.

As constructive variants, suggested for cases in that the user has restrictions for the touch in a simulation of part of the human body, the form of the device simulator of the feminine mammary gland can be represented in a stylized way, like a half of a pear or of a drop or still to a solid whose base is a triangle, a circle, etc., or any solid that can represent, although symbolically, the feminine mammary gland.

The external coating of the flexible cover (4) it can be colored in any shade and tonality, from the several tones of human skin or any other color, its variations and combinations.

The body 1 of the human female breast model of the present invention may comprise a variety of shapes, including a half-pear shaped or half-teardrop shape to replicate the shape of a human female breast. The body (1) of the human female breast model also may be constructed on a base (2) having a triangular, circular, polygonal, or other shape and configuration to represent the human female breast.

In another embodiment of the invention, a costal arch (20) may be inserted within one of the quadrants to be chosen, preferably that one that doesn't show any pathology simulator element, a B, C, D, E of the body (1) to represent a rib. In this embodiment, the costal arch can be inserted, in rigid material, hiding a rib. into a quadrant that does not include a pathological simulator element.

It will be understood that several modifications can be introduced without leaving the patent field of protection, being able to substitute some elements by others that would has the same technical characteristics.

While the invention has been disclosed in this patent application by reference to the details of preferred embodiments of the invention, it is contemplated that a variety of modifications can be made, including substitution elements, as will readily occur to those skilled in the art, within the spirit of the invention and the scope of the claims.

5

CLAIMS

1. "SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND", to guide patient, nurses, doctors and the whole personnel of the medical, educational area and lay population in the detection of pathological occurrences, by touch, characterized by a
5 body (1), put upon to a base (2) made by rigid material, as plastic, metal, wood, formic, leather, rubber, etc., serving as support to the stuffing material (3) that gives volume to the body (1); the stuffing material is normally prepared with many different material like small particles, as grains, flakes, seeds, sawdust, sands, flour, cotton, floss, plastic, scum, silicon, rubber, light metal, etc., or gelatinous, gaseous or liquid material, or still
10 others that stimulate the inside tissue of the mammary gland, having a texture that allows the observation, for the touch, of the elements (5.a) and (5.b) simulators of existent pathologies inside the body (1).
2. "SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND", according to claim 1, characterized by the simulators elements of existent pathologies
15 inside the body (1), are fixed (5a) in the base (2) or in the stuffing material (3), simulating rigid pathologies, in an irregular and angular way, made with rigid material, and untiled (5b) from the base (2), floating in the stuffing material (3), simulating non fasten pathologies, in spherical or round ways, of smooth aspect, made in malleable material, inside an elastic spherical film.
- 20 3. "SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND", according to claim 1, characterized by the cover (4) of the body (1) be divided in five defined areas (A, B, C, D, E), representing the pigmented areola (6), whose area is

represented in four quadrants (A1, A2, A3 and A4), the nipple (7) and the remaining area of the gland represented in another four quadrants (B, C, D and it is).

4. "SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND",

according to claim 1, characterized by the nipple (7) having elements (5c, 5d, and 5e)

5 pathology simulators, corresponding to the emersion of three secretion types after being the nipple pressed or not with the fingers.

5. "SIMULATOR DEVICE FOR HUMAN FEMININE MAMMARY GLAND",

according to claim 1, characterized by characterized for the body (1) can be fastened in

a rigid frame (8), endowed with lowering (9) in its central part for the fitting of the body

10 (1), that should contain spaces (10) for orientations, as well as spaces (11) for any information of public interest and publicity.

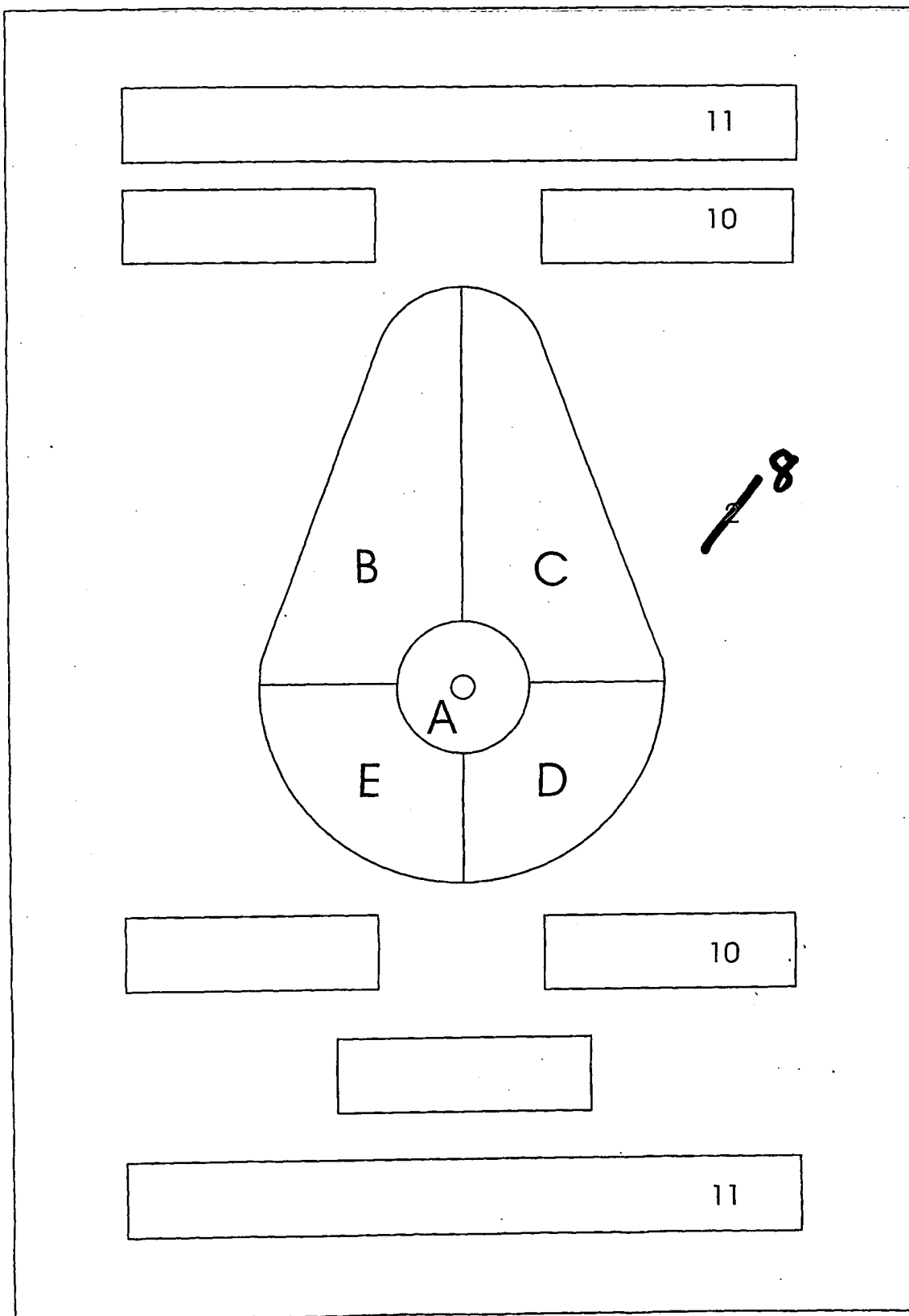
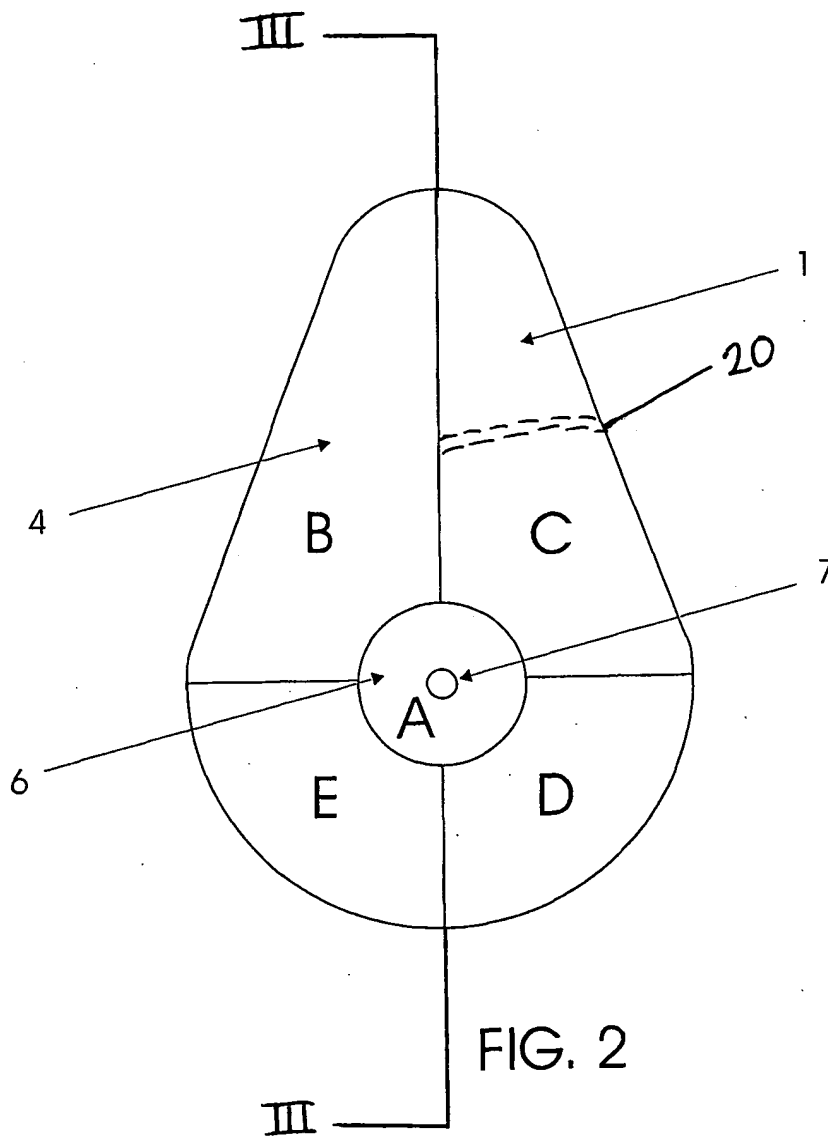
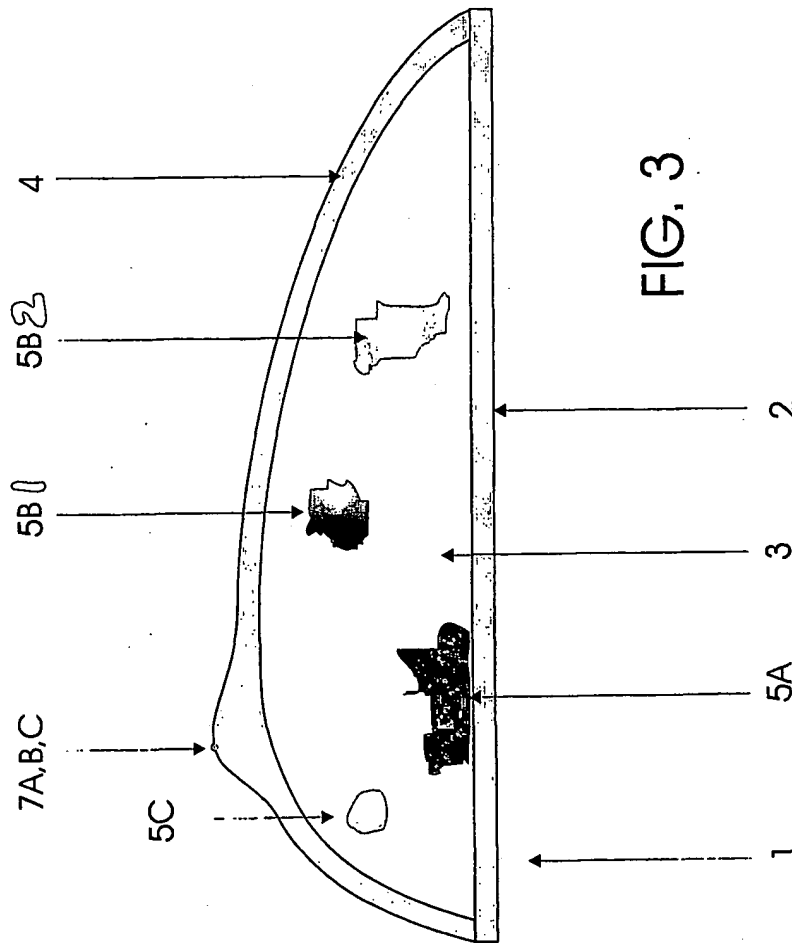
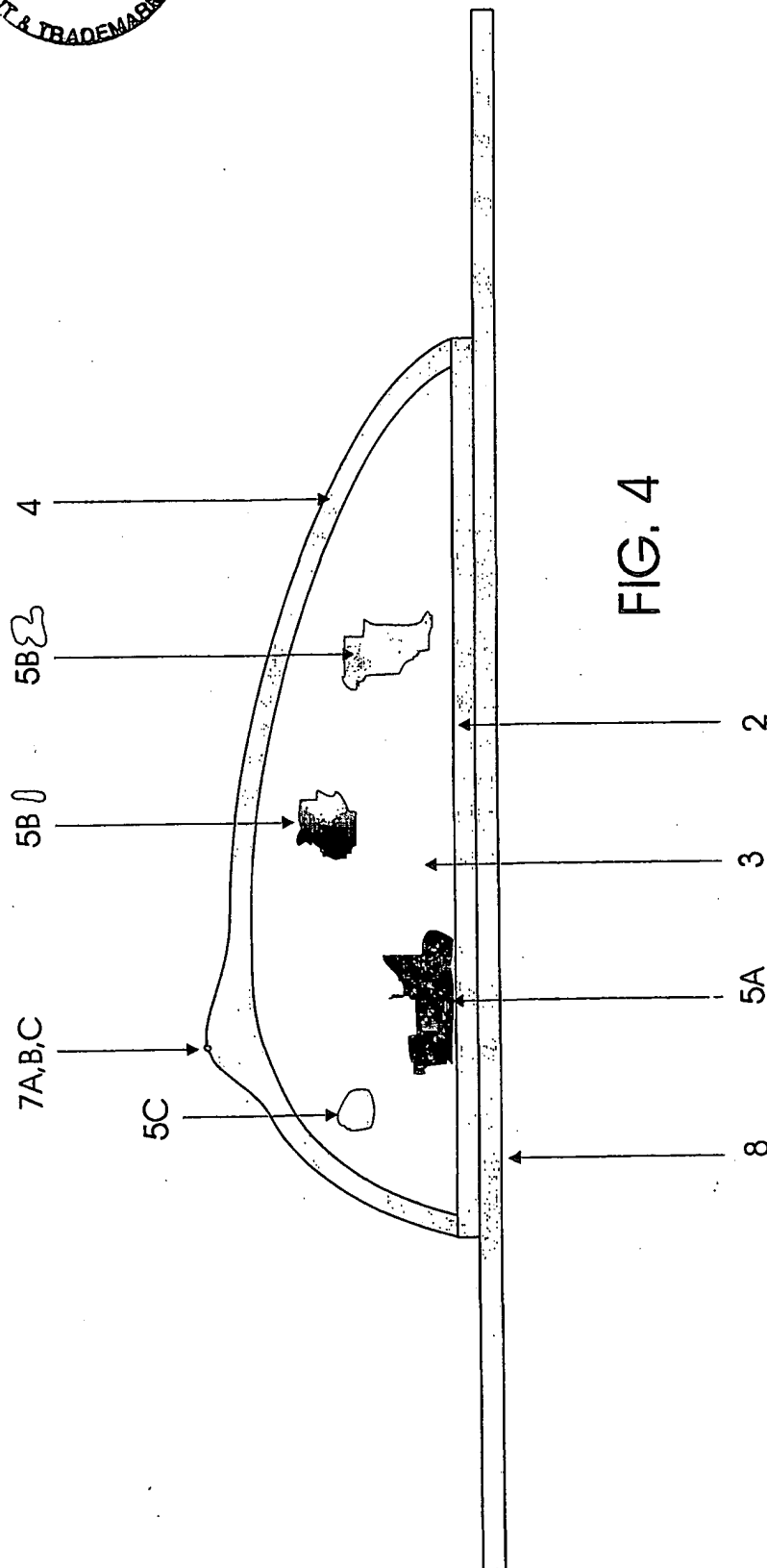


FIG. 1







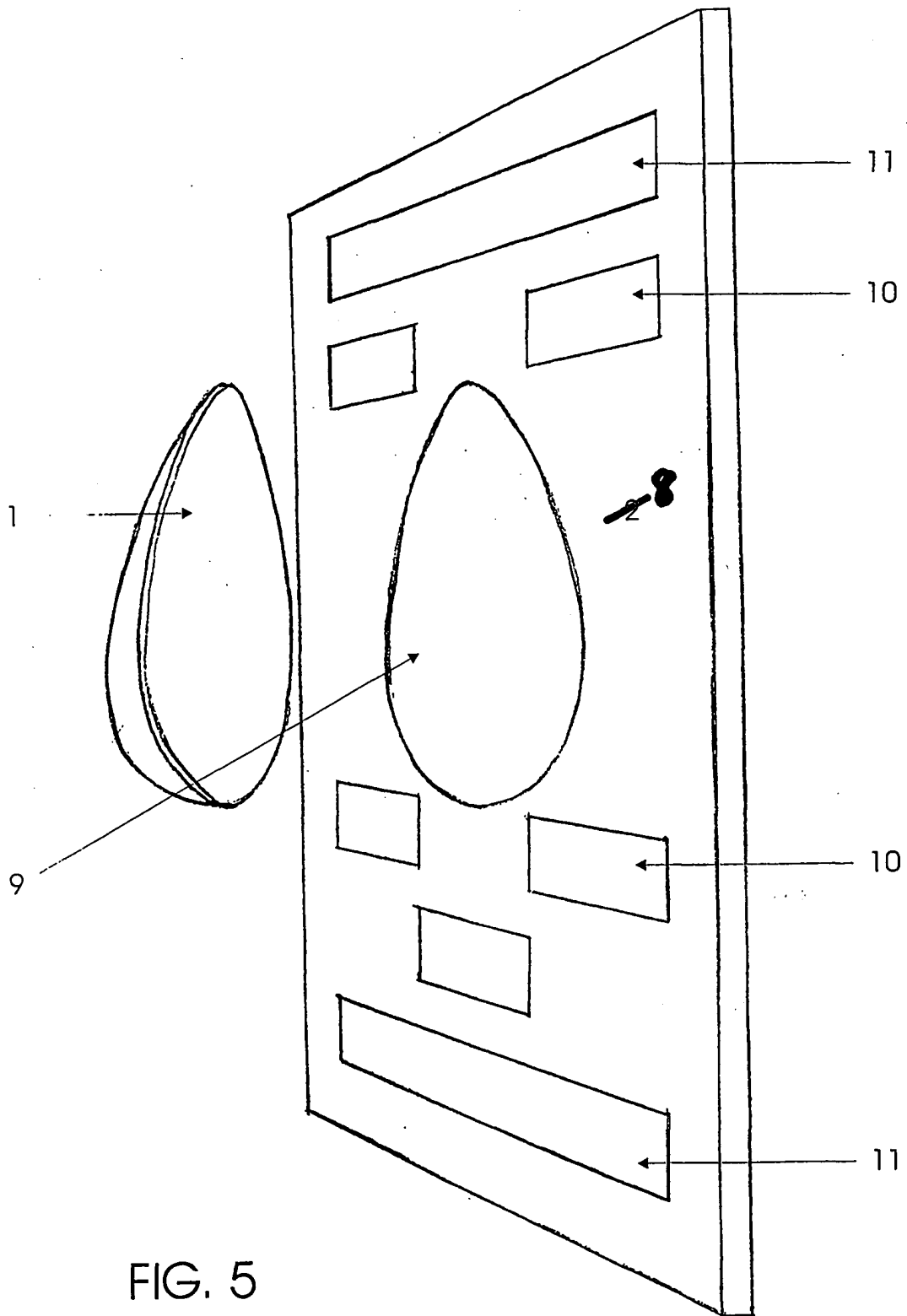
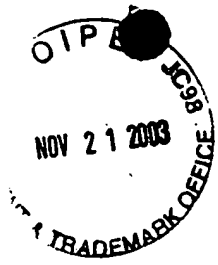


FIG. 5